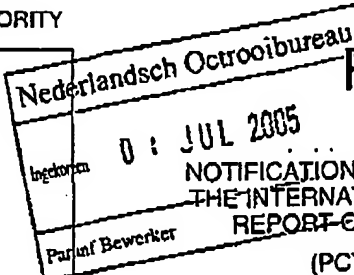


## PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

VAN WESTENBRUGGE, Andries  
Nederlandsch Octrooibureau  
Scheveningseweg 82  
P.O. Box 29720  
NL-2502 LS The Hague  
PAYS-BAS



preliminary examination report

rapporten aan cliënt:

29-7-05

termijn omzetten in reg./nat. fase:

PCT 5-2-06

Date of mailing  
(day/month/year)

29.06.2005

Applicant's or agent's file reference  
P045479PCT

### IMPORTANT NOTIFICATION

International application No.  
PCT/NL2004/000551

International filing date (day/month/year)  
04.08.2004

Priority date (day/month/year)  
05.08.2003

Applicant  
FUJI PHOTO FILM B.V. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:



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## PATENT COOPERATION TREATY

## PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

|  |   |  |
|--|---|--|
| Applicant's or agent's file reference<br>P045479PCT  | <b>FOR FURTHER ACTION</b> See Form PCT/PEA/416  |  |
| International application No.<br>PCT/NL2004/000551   | International filing date (day/month/year)<br>04.08.2004  | Priority date (day/month/year)<br>05.08.2003 |
| International Patent Classification (IPC) or national classification and IPC<br>A61K47/34, A61K39/00   |   |  |
| Applicant<br>FUJI PHOTO FILM B.V. et al.   |   |  |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 807 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> |   |  |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>   |   |  |
| Date of submission of the demand<br><br>25.03.2005   | Date of completion of this report<br><br>29.06.2005   |  |
| Name and mailing address of the international preliminary examining authority:<br><br> European Patent Office<br>D-80288 Munich<br>Tel. +49 89 2399 - 0 Tx: 523656 epmu d<br>Fax: +49 89 2399 - 4465  | Authorized Officer<br>Telephone No. +49 89 2399-<br> |  |

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**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**International application No.  
PCT/NL2004/000551**Box No. I Basis of the report**

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the elements\* of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*.

**Description, Pages**

1-15 as originally filed

**Claims, Numbers**

1-17 as originally filed

**Drawings, Sheets**

1/3-3/3 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**International application No.  
PCT/NL2004/000551

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

|                               |             |      |
|-------------------------------|-------------|------|
| Novelty (N)                   | Yes: Claims |      |
|                               | No: Claims  | 1-17 |
| Inventive step (IS)           | Yes: Claims |      |
|                               | No: Claims  | 1-17 |
| Industrial applicability (IA) | Yes: Claims | 1-17 |
|                               | No: Claims  |      |

**2. Citations and explanations (Rule 70.7):**

see separate sheet

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.

**PCT/NL2004/000551**

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement**

The following documents are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1 (WO 01 34 801 A), disclosing the preparation of recombinant gelatines for vaccines and the vaccines obtained, also in dry form;  
D2 (US 2003 064 074 A), disclosing the preparation of recombinant gelatines for vaccines;  
D3 (Godard P et al, Journal of Polymer Science, 1978, vol. 16, no. 10, pages 1817-1828), disclosing the dependency of the gelation (crystallisation) and melting behaviour of aqueous gelatin on temperature, concentration and molecular composition;  
D4 (Apostolov A. A. et al: Journal of Applied Polymer Science, (1999), 71(3), 465-470); disclosing the behaviour of water molecules in gelatin: crystallization behaviour and effects on gelation.

Unless otherwise indicated, reference is made to the relevant passages emphasized in the Search Report.

**1. Novelty**

The present set of claims 1-17 does not appear to be novel as required by Art. 33(1) and (2) PCT over D1. In fact, D1 discloses the advantages (in terms of immunogenicity and infection risks) of the use of recombinant/synthetic gelatines, also as mixtures of polymers with different molecular weights, for the preparation of vaccine compositions with respect to the natural products. Moreover, although the limit of 2% water content is not mentioned, the vaccines are said to be obtainable also in dry or freeze-dried/lyophilized form. These forms are considered to implicitly disclose a very low (<2%) water contents. Therefore, D1 is novelty destroying for claims 1-17.

**2. Inventive step**

Even if claims 1-17 could be rendered novel by the restriction to a particular embodiment,

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.

PCT/NL2004/000551

their inventiveness according to Art. 33(1) and (3) PCT could not be acknowledged. The problem is to provide a process which allows to obtain a particularly stable preparation. D1 and D2, which can be considered the closest prior art items, disclose the use of recombinant gelatin as a stabilizer for vaccine preparations. The difference in the present application is the mention of a very low water contents. However, in particular D3 shows that increasing water concentrations lower the temperature at which the physico-chemical properties of gelatin change (gelation/crystallization). It would therefore be obvious for the skilled person wanting to improve the vaccine shelf-life to reduce the water contents in the preparation.